Appln. No.: 10/080,791

Amendment Dated October 26, 2005 Reply to Office Action of June 27, 2005

Amendment to the Specification:

Please amend the applicants' specification as originally filed, as follows:

Please add the following $\underline{\text{new}}$ paragraph prior to the $\underline{\text{DETAILED DESCRIPTION OF THE}}$ $\underline{\text{INVENTION}}$ on page 6:

Fig. 7 is an illustration of a further exemplary embodiment of the invention.

Please revise the paragraph beginning on page 8, line 330, of the originally filed specification to read:

Anchoring step 350 may be accomplished using any mechanism that prevents significant displacement of the proximal end while the distal end is being deployed. Anchoring can be accomplished using the stent's own radial force, or by using additional anchoring means such as hooks, barbs, balloons, tethers, and notch-and-loop arrangements, many of which are discussed in the BSI-486US Application Application Serial No. 10/081,641 ("the '641 Application).

Please add the following <u>new</u> five (5) paragraphs to applicants' specification by inserting them before the paragraph beginning on page 9, line 5, of the application as originally filed. This text has been excerpted with only minor changes from p. 3, line 26-p. 4, line 19 and p. 12, lines 3-30 of Application Serial No. 10/081,641, filed February 2, 2002, the subject matter of which was previously incorporated by reference into the applicants' specification as originally filed. This amendment therefore does not constitute addition of new matter:

In one embodiment, discussed in more detail in the '641 Application and later in this application, the anchoring mechanism for preventing significant displacement of the proximal end while the distal end is being deployed comprises an inflatable balloon in the retrograde portion.

In another embodiment, discussed in more detail in the '641 Application, the anchoring mechanism comprises a holder in the anterograde portion. The holder may be concentrically mounted to the inner sheath and adapted to prevent distal movement of the endoluminal device during advancement of the anterograde shaft. A number of geometries and materials useful for holding a stent in place from inside the stent are described in U.S. Application Serial No. 09/574,418 by Sullivan et al., filed on May 19, 2000, assigned to the assignee of this invention, and incorporated herein by reference. For example, the holder may be a sleeve of a relatively higher friction material than the sheath over the device such that device is frictionally retained while the sheath advances. In another embodiment, the holder may comprise one or more radial protrusions that exerts an axial restraining force against individual members of device. Other structures or combinations of multiple structures may also be used as holders. A hybrid may also be provided comprising both a holder and a balloon or other anchoring means at the proximal end of the device.

In another embodiment, discussed in more detail in the '641 Application, the introducer comprises the proximally retractable retrograde sheath and the medial sheath, wherein the anchoring mechanism comprises an extended portion of a proximal end of the endoluminal device and a notch in one or both of the medial sheath and the

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retrograde sheath for releasably confining the extended portion between the retrograde sheath and the medial sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the medial sheath.

In yet another embodiment, discussed in more detail in the '641 Application, the anchoring mechanism comprises a tether attached to a proximal end of the endoluminal device. In an embodiment comprising the proximally retractable retrograde sheath and the medial sheath, the tether may be attached to one of the medial sheath, the retrograde sheath, or the inner sheath. In another embodiment, the tether may extend proximally from the device a sufficient distance to terminate outside a body lumen through which the introducer is adapted to be introduced. In such an embodiment, the medial sheath may comprise a lateral channel through which the tether extends.

Please revise the paragraph beginning on page 9, line 23, of the specification as originally filed to read:

Radial space 118 between retrograde sheath 112 and inner sheath 108 may be sufficiently large to allow room for a radial-force-exerting device, such as balloon 120. Inner sheath 108 preferably has a fixed position and may include a lumen for communicating pressurized fluid to balloon 120. Although shown in Fig. 4 with balloon 120 and proximal end 131 of device 130 as part of retrograde portion 102 covered by retrograde sheath 112, in an alternative embodiment—(not shown), shown in Fig. 7, balloon 120 and proximal end 131 of device 130 may be part of anterograde portion 104 covered by anterograde sheath 126.